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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/128,340	08/03/1998	OSCAR J. LLORIN	P-4278	2600

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EXAMINER
WARE, DEBORAH K

ART UNIT	PAPER NUMBER
1651	24

DATE MAILED: 09/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/128,340	LLORIN ET AL.	
	Examiner	Art Unit	
	Deborah K. Ware	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *30 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

In accordance with 37 CFR 1.196(a) the instant application has been remanded to the examiner for further consideration. Thus, prosecution is reopened in order that the claims may be further considered on the merits.

Claims 1 and 3-~~8~~7 are pending.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 3-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buck ét al. (ctied of record) in view of Robson et al (cited of record), newly cited Nanba et al. (cited on enclosed PTO-892 Form), newly cited Kubota et al. (cited on enclosed PTO-892 Form) and newly cited Chang (cited on enclosed PTO-892 Form).

Claims are discussed of record.

Buck et al. Is discussed of record. Buck does not disclose the use of beads during disrupting using sonciation and this point has been made of record.

Robson et al teach use of elevated temperature such as heated water baths to disrupt cells (note column 2, lines 1-2: "lysis effective amount of heat refers to that amount of elevated temperature") also note column 5, lines 55-57: "Heating means include water baths". Further, note the cells are sonicated at 60 degrees Celsius, see column 8, lines 1-2. Also noted of record is that the sonciation may be performed in the presence of beads and in the absence of beads.

Nanba et al disclose disrupting cells contained in an alkaline liquid by sonication, note column 9, lines 63-65: "After adjusting the pH to 8.5 with ammonia water, the cells were disrupted by sonication".

Kubota et al teach treating Mycobateria cells with an ultrasonic disintegrator in the presence of a surfactant, note column 11, lines 39-41: "in the case of treating the cells with an ultrasonic disintegrator, they may be treated in the presence of a surfactant".

Chang teaches at page 81, lines 13-15, that any substance that causes a reduction in surface tension is called a surfactant.

The claims differ from the disclosure of Buck et al. in that the following are not disclosed: a second liquid at an alkaline pH , a first liquid at a temperature between about 65 to 75 degrees Celsius, or the surface tension of said second liquid is reduced.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to adjust the second liquid (residual water) of Buck et al.

with ammonia to provide for an alkaline pH as dislosed by Nanba et al. and further to elevate temperatures to 65 degrees Celsius as suggested by Robson, and to also add a surfactant to the second liquid of Buck during sonciation in which to reduce surface tension of the second liquid as disclosed by Kubota et al and Chang. Buck et al clearly teach the desire in the prior art to improve upon well known procedures in the art of cell disruption, and further teach that sonication is effective for achieving such improvements.

Adding surfactants for purposes of disrupting cells is also disclosed by Buck and further to do so during sonciation is also disclosed by Kubota et al. Therefore, one of skill in the art would have been motivated to provide for a method for disrupting cells comprising sonciation as disclosed by Buck et al using a second liquid at an alkaline pH and further adding a sufactant thereto as the same are disclosed as being useful for the sonication of cells.

The reduction of surface tension of the second liquid would have been an expected successful result upon providing a surfactant as disclosed by Kubota et al, and as evidenced by the teaching of Chang. Mycobacteria are clearly disclosed by Buck et al. and Robson and Kubota (see Kubota at column 11, line 28). To modify the second liquid of Buck et al. as taught by Nanba et al and Kubota et al. is clearly within the purview of an ordinary artisan. No unexpected successful result has been obtained and the combination of claimed method steps are clearly suggested, if not taught, by the cited prior art. Thus, the claims are *prima facie* obvious over the newly cited prior art combination.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 8 is rejected under 35 U.S.C. 102(e) as being anticipated by Kubota et al in light of Chang (both reference cited and discussed above).

Claim is drawn to a method for disrupting cells by applying ultrasonic energy to a sample of cells in a first liquid, wherein the surface tension of said first liquid is reduced.

Kubota et al teach a method for disrupting (i.e. lysing) cells by applying ultrasonic energy to a sample of Mycobacteria cells in the presence of a surfactant (i.e. SDS (sodium dodecyl sulfate)). Note column 11, line 28 for the teaching of Mycobacteria if desired, however, claims of instant case are not limited to Mycobacteria in claim 8.

The claim is identical to the cited disclosed teaching above by Kubota et al, and surface tension would be reduced by a liquid in the presence of a surfactant as

evidenced by Chang, discussed above. Therefore the claim is considered to be anticipated by the teaching of Kubota et al.

Claims 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buck et al. in view of Kubota et al., Chang, Robson et al., Nanba et al, all discussed above and cited on enclosed PTO-892 Form.

Claims are further drawn to a method for disrupting cells wherein the first liquid is at a alkaline pH and contains beads and the first liquid is contained in a vessel and the vessel is in a sonic bath comprising a second liquid which is at a temperature of about 65 to 75 degrees Celsius. Further, the cells are mycobacteria.

All references are discussed above.

The claims differ from Buck in that the first liquid is not at an alkaline pH nor a reduced surface tension, and does not contain beads and the temperature of the second liquid is not disclosed to be at 65 to 75 degrees Celsius.

It would have been obvious to one of ordinary skill in the art at the time the claimed method was made to adjust the first liquid (residual water) of Buck et al. with ammonia to provide for an alkaline pH as dislosed by Nanba et al. and further to elevate temperatures to 65 degrees Celsius as suggested by Robson, and to also add a surfactant to the first liquid of Buck during sonciation in which to reduce surface tension of the first liquid as disclosed by Kubota et al and Chang. Buck et al clearly teach the desire in the prior art to improve upon well known procedures in the art of cell disruption, and further teach that sonication is effective for achieving such improvements.

Adding surfactants for purposes of disrupting cells is also disclosed by Buck and further to do so during sonciation is also disclosed by Kubota et al. Therefore, one of skill in the art would have been motivated to provide for an method for disrupting cells comprising sonciation as disclosed by Buck et al using a first liquid at an alkaline pH and further adding a sufactant thereto as the same are disclosed as being useful for the sonication of cells.

The reduction of surface tension of the first liquid would have been an expected successful result upon providing a surfactant as disclosed by Kubota et al, and as evidenced by the teaching of Chang. Mycobacteria are clearly disclosed by Buck et al. and Robson and Kubota (see Kubota at column 11, line 28). To modify the first liquid of Buck et al. as taught by Nanba et al and Kubota et al. is clearly within the purview of an ordinary artisan. Further to provide beads as disclosed by Robson (note column 8, lines 58-59) in the first liquid is also an obvious modification and cell disruption would have also been expected to take place in their presence especially those undergoing ultrasonic disruption. No unexpected successful result has been obtained and the combination of claimed method steps are clearly suggested, if not taught, by the cited prior art. Thus, the claims are *prima facie* obvious over the newly cited prior art combination.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 308-4245. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0196.

Deborah K. Ware
August 29, 2003

DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651